

P A T E N T

UNITED STATES PATENT AND TRADEMARK OFFICE

In re: William S. Henry et al. Confirmation No.: 7622
Serial No.: 10/764,054 Examiner: Kevin Thao Truong
Filing Date: January 23, 2004 Group Art Unit: 3734
Docket No.: 1001.1718101 Customer No.: 28075
For: STENT DELIVERY CATHETER

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

CERTIFICATE FOR ELECTRONIC TRANSMISSION:

The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 8th day of October 2007.

By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this Request.

This Request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached five sheets of arguments.

This Request is signed by an attorney or agent of record.

Respectfully submitted,

William S. Henry et al.

By their Attorney,

Date: 10/8/07

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Attachment: Five Sheets of Pre-Appeal Brief Request Attachment

P A T E N T

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PRE-APPEAL CONFERENCE BRIEF

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By Kathleen L. Boekley
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Dear Sir:

Appellants have carefully reviewed the Final Office Action dated May 16, 2007 and the Advisory Action dated August 7, 2007. Currently, claims 1-19 are pending in the application, wherein the Examiner has rejected all pending claims. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a *prima facie* rejection.

Claims 1-19 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lenker et al., EP 0 696 447 A2. Applicants submit that the Examiner has not met his burden of providing a reference that teaches each and every element of the claims, as is required for anticipation.

MPEP 2131 states that, in order to anticipate a claim, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)." Thus, the part-to-part relationship of components must be considered when evaluating claims. See *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Lenker et al. do not teach each and every structural limitation of the claimed invention, thus the Examiner's reliance on Lenker et al. as anticipating the claims is in error.

Claim 1 recites:

A self-expanding stent delivery assembly comprising:
a shaft having a distal region and a longitudinal axis;
a retractable sheath having a proximal end and a distal end, the retractable co-axially disposed around at least the shaft distal region;
a stent disposed co-axially between the shaft and the retractable sheath in the distal region;
a stop member coupled to the shaft and positioned proximally of the stent; and
a tubular tapered tip affixed to the retractable sheath distal end, the tubular tapered tip having an elongate region predisposed to fracturing.

Emphasis added. The Examiner asserts that Figures 1-5 and 31 of Lenker et al. disclose the claimed invention. The Examiner is equating the plurality of penetrating stay members 50 of Lenker et al. with the claimed stop, and asserts that Lenker et al. teach "a stop (50) coupled to the shaft (34) and positioned proximally of the stent (P)". See Office Action mailed May 16, 2007, at page 2, paragraph 2. Figures 2-4 of Lenker et al. show the penetrating stays 50 engaging a region of prosthesis P distal of the proximal end. Lenker et al. teach:

In the embodiment of Fig. 2, the prosthesis P is anchored by a plurality of penetrating stay members 50 which are circumferentially spaced-apart over the exterior of the shaft 34. The stays 50 will be spaced proximally from the distal end 42 of the shaft 34 by a distance which corresponds generally to that of the tubular prosthesis P which is to be maintained on the delivery catheter 30. The penetrating stays 50 will extend radially outward by a distance sufficient to engage the interior surface of the lumen 36 of the sheath 32. In that way, the penetrating stays 50 will be able to anchor the proximal end of the tubular prosthesis [sic] P when it is held within the catheter. In particular, the prosthesis P will remain anchored as the sheath 32 is drawn proximally over the shaft 34, as illustrated in Figs. 3-5.

When initially placed in a body lumen L, the sheath 32 covers substantially the entire length of the prosthesis P with the penetrating stays 50 engaging the proximal portion of the prosthesis P, as illustrated in Fig. 3. The sheath 32 may then be retracted proximally, partially releasing the prosthesis P, as illustrated in Fig. 4. The proximal portion of the prosthesis P, however, remains anchored by the penetrating stays 50 so long as the sheath 32 remains positioned over the stays.

Emphasis added; see column 13, lines 12-35. The specific teachings and figures of Lenker et al. do not teach "a stop member coupled to the shaft and positioned proximally of the stent, as is recited in independent claim 1 and the claims dependent thereon.

If the Examiner is considering the specific elements of the claims to be inherent in Lenker et al., Applicants submit that there is no basis for such an interpretation. MPEP 2112 IV. states:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is **necessarily present** in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

(Emphasis added). Applicants submit that all the claimed elements, in particular the stop member positioned proximally of the stent, are not necessarily present in Lenker et al. As taught by Lenker et al., the location of the penetrating stay members 50 allows the stay members 50 to extend through openings of the stent 50. Thus, some portion of the stent P must be located proximally of the stay members 50. Shown positioned between adjacent coils of the stent P, "the penetrating stays 50 will be able to anchor the proximal end of the tubular prosthesis P when it is held within the catheter." Lenker et al., at column 13, lines 21-24. Thus, as the penetrating stay members 50 are located distal of the proximal end of the stent P, the penetrating stay members 50 cannot be said to be positioned proximally of the stent, as currently claimed. The Examiner is asserting that the device of Lenker et al. could be adapted or modified to include the recited claim elements, which is not a proper basis for rejection under 35 U.S.C. § 102(b).

Furthermore, the Examiner is relying on Figure 31 of Lenker et al. as disclosing a tubular tapered tip having an elongate region predisposed to fracturing, as currently claimed. Applicants assert that Lenker et al. do not teach these structural features at Figure 31. Regarding Figure 31, Lenker et al. state:

Referring now to Fig. 31, an alternative cover 480 provides an atraumatic distal end 482 with a reduced nosecone diameter, or, alternatively, no nosecone at the distal end of core shaft 444. Atraumatic cover 480 includes a series of splits 484 to allow the distal tip of atraumatic cover 480 to open during deployment of prosthesis 10.

Emphasis added; see column 21, lines 28-34. Thus, the cover 480 includes a plurality of splits 484 in the cover 480.

Applicants assert that the splits or cuts 484 in the cover 480 of Lenker et al. are not equivalent to the "elongate region predisposed to fracturing" as currently claimed. The claimed "elongate region predisposed to fracturing" describes a region of the claimed tapered tip which is

susceptible to being broken or separated, yet is not broken or separated prior to deployment of the stent. Applicants note that the present description describes three possible regions predisposed to fracturing at lines 3-8 of page 8. These three examples of an elongate region predisposed to fracturing are also claimed in claims 3 through 5. The present description states:

In an illustrative embodiment, the elongate region predisposed to fracturing 90 can be a line of perforations that extend through a portion of or through the entire tubular tip 36 wall thickness. The elongate region predisposed to fracturing 90 can be a score line that extends through a portion of the tubular tip 36 wall thickness where the wall thickness along the score line 90 is less than the thickness along the remaining tubular tip 36 wall. Alternatively or in addition, the elongate region predisposed to fracturing 90 can be material having a tensile strength that is less than the tensile strength of the remaining tubular tip 36.

Thus, it can be seen that the claimed elongate region predisposed to fracturing is a region of material which holds adjacent portions of the tip together prior to being fractured, yet is a region which is susceptible to being broken into separate adjacent portions of the tip at a determined time. To the contrary, the splits 484 in the cover 480 of Lenker et al. represent areas where the cover 480 has already been separated into discrete sections. Because the cover 480 has already been split, no further "fracturing" is taught or contemplated by Lenker et al.

In the Advisory Action mailed August 7, 2007, the Examiner asserts that the slits of Lenker et al. are clearly equivalent to "predisposed to fracturing" due to the definition of "fracture", which includes the entry, "a break, breach, or split". The Examiner is ignoring a key portion of the claim language, i.e., "predisposed to", and is interpreting the claim as reciting a region that is fractured. Such a claim interpretation is in error. The claim actually recites "an elongate region predisposed to fracturing." The definition of "predispose" according to the Merriam-Webster online dictionary is:

Main Entry: pre·dis·pose
Pronunciation: "prE-di-'spOz
Function: verb
transitive verb
1 : to dispose in advance <a good teacher *predisposes* children to learn>
2 : to make susceptible <malnutrition *predisposes* one to disease>
intransitive verb : to bring about susceptibility

Emphasis added. The claimed phrase, "predisposed to fracturing", thus cannot be seen to mean already split, as is the Examiner's interpretation. For at least these reasons, the Examiner's reliance on Lenker et al. as anticipating claim 1 is in error.

Applicants note that the Final Office Action includes no explanation as to where Lenker et al. teach the limitations in claims 2-10. For example, there is no explanation as to where Lenker et al. teach an elongate region predisposed to fracturing is a line of perforations as claimed in claim 2, or where Lenker et al. teach an elongate region predisposed to fracturing which has a thickness less than the thickness of the tubular tip as claimed in claim 3, or where Lenker et al. teach an elongate region predisposed to fracturing which is formed of a material having a tensile strength less than the tensile strength of the material forming the tubular tip as claimed in claim 4. Applicants note that the Examiner has an obligation to clearly state the grounds for rejecting each of the claims in every Office Action. See M.P.E.P. §707.07(d). The Examiner has not met this obligation, thus the rejection of the dependent claims is in error.

Applicants assert Lenker et al. do not teach the limitations of the method of claim 11, in particular that of "fracturing the elongate region predisposed to fracturing." There is no discussion in Lenker et al. of fracturing the slits 484 of the cover 480 which would meet the limitations of claim 11. For at least the above reasons, the rejection of claim 11 as being anticipated by Lenker et al. is believed to be in error. The Examiner has failed to address the specific elements of dependent claims 12-19, thus their rejection is also in error.

For at least the reasons mentioned above, it is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

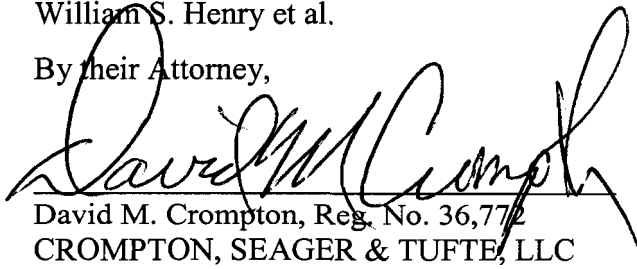
Date: _____

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Respectfully submitted,

William S. Henry et al.

By their Attorney,



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